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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,126	07/17/2006	Pascual Perez	11887-00008-US	2989
23416 7590 08/18/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER KALLIS, RUSSELL				
ART UNIT 1638		PAPER NUMBER		
MAIL DATE 08/18/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,126

Applicant(s)

PEREZ ET AL.

Examiner

RUSSELL KALLIS

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15 and SEQ ID NO: 1 in the reply filed on 5/06/2009 is acknowledged. The traversal is on the ground(s) that SEQ ID NO: 1, 2, 3 and 62 share a common 'pattern' with SEQ ID NO: 57. This is not found persuasive because the special technical feature as stated in the requirement for restriction filed 3/06/2009 was taught in the art.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to because they are poor photocopies of gel-photos and are not suitable for publication.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to isolated polynucleotide sequences that have endosperm specific promoter activity and transformed plant cells and plants thereof and methods thereby.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant describes SEQ ID NO: 1 having endosperm specific activity.

Applicant does not describe those features when taken together that would define a genus comprising SEQ ID NO: 1 having endosperm specific activity.

Applicants fail to describe a representative number of isolated polynucleotide sequences having endosperm specific activity. Applicants only describe MEG1-1 and MEG1-2 (i.e. SEQ ID NO: 1 and SEQ ID NO: 2). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of isolated polynucleotide sequences having endosperm specific activity. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for endosperm specific activity, it remains unclear what features identify instantly claimed genus of sequence that hybridize to SEQ ID NO: 1 or sequences having at least 70% sequence identity or a sequence that comprises a nucleotide sequence that is conserved among the sequences of the instant claims. Since the genus of endosperm specific promoter

polynucleotides sequences has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Sequences that hybridize with SEQ ID NO: 1 and which are 70% complementary to SEQ ID NO: 1 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 1, as well as sequences encoding proteins having no known endosperm specific promoter activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of endosperm specific promoter polynucleotides encompassed by the hybridization language or percent identity language as set forth in the claims.

For example, the following sequence alignments are of MEG1-1, MEG1-2 and MEG1-3 respectively. The sequence that are underlined are from Gutierrez-Marcos, J, *et al.* The Plant Cell 2004; Vol. 16, No. 5, pp. 1288-1301; wherein the authors provide in Figure 6 on page 1294 4 conserved regions found in MEG1 and other endosperm specific promoters. Figure 2 on page 1290 of the same publication indicates that only MEG1-1 and MEG1-2 are endosperm specific. However, the comparison below shows that MEG1-2 has elements more in common with MEG1-3 i.e. BOX III; and thus it appears that there are other unknown elements providing endosperm specific promoter activity than those described in Applicants' specification.

```
RESULT 1
US-10-578-126-1
; Sequence 1, Application US/10578126
; GENERAL INFORMATION:
; APPLICANT: Perez, Pascual
; APPLICANT: Gutierrez-Marcos, Jose
; APPLICANT: Dickinson, Hugh
; TITLE OF INVENTION: MEG1 Endosperm-Specific Promoter and Genes
; FILE REFERENCE: 11887*8
; CURRENT APPLICATION NUMBER: US/10/578,126
; CURRENT FILING DATE: 2006-05-02
; PRIOR APPLICATION NUMBER: PCT/EP04/052760
; PRIOR FILING DATE: 2004-11-04
; PRIOR APPLICATION NUMBER: EP 03292739.4
```

Art Unit: 1638

```
; PRIOR FILING DATE: 2003-11-03
; NUMBER OF SEQ ID NOS: 64
; SOFTWARE: PatentIn version 3.2
; SEQ ID NO 1
; LENGTH: 370
; TYPE: DNA
; ORGANISM: Zea mays
; FEATURE:
; NAME/KEY: misc_feature
; OTHER INFORMATION: promoter Meg1-1
US-10-578-126-1
```

```
Query Match          100.0%; Score 370; DB 46; Length 370;
Best Local Similarity 100.0%; Pred. No. 8.3e-93;
Matches 370; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 AGCCAGAATTGTAACCTTGGGTTTCCCACACCTCAAATAGATATGGATATAGTTATATA 60
Db      1 AGCCAGAATTGTAACCTTGGGTTTCCCACACCTCAAATAGATATGGATATAGTTATATA 60

Qy      61 GATAGATATAGCAAATTCACCAATAATATAGAGGTATAGATATAGATATAACAAGGGGT 120
Db      61 GATAGATATAGCAAATTCACCAATAATATAGAGGTATAGATATAGATATAACAAGGGGT 120

Qy      121 ATATATATAGATATAGATATATAGAAGATATAGATGGATAGATAGATATGATAGATAGA 180
Db      121 ATATATATAGATATAGATATATAGAAGATATAGATGGATAGATAGATATGATAGATAGA 180

Qy      181 ATAGATAACTTACAATTTTGCTAAAAGAGACTAAATCACTGCTAAGTTTGGTCTTTGGT 240
Db      181 ATAGATAACTTACAATTTTGCTAAAAGAGACTAAATCACTGCTAAGTTTGGTCTTTGGT 240

Qy      241 GAATACTTGCCAGTGAATTGGTTTTCGCTATAGTATATATATAAGTATACACTCTTCTAG 300
Db      241 GAATACTTGCCAGTGAATTGGTTTTCGCTATAGTATATATATAAGTATACACTCTTCTAG 300

Qy      301 GATTATAGTATATATAAGTATACACTCTTCTAGGATCGGTCGTGAGGAGTTCCCTTAACAT 360
Db      301 GATTATAGTATATATAAGTATACACTCTTCTAGGATCGGTCGTGAGGAGTTCCCTTAACAT 360

Qy      361 TTCTTGCGAC 370
Db      361 TTCTTGCGAC 370
```

RESULT 2

US-10-578-126-2

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; Sequence 2, Application US/10578126
; GENERAL INFORMATION:
; APPLICANT: Perez, Pascual
; APPLICANT: Gutierrez-Marcos, Jose
; APPLICANT: Dickinson, Hugh
; TITLE OF INVENTION: MEGL Endosperm-Specific Promoter and Genes
; FILE REFERENCE: 11887*8
; CURRENT APPLICATION NUMBER: US/10/578,126
; CURRENT FILING DATE: 2006-05-02
; PRIOR APPLICATION NUMBER: PCT/EP04/052760
; PRIOR FILING DATE: 2004-11-04
; PRIOR APPLICATION NUMBER: EP 03292739.4
; PRIOR FILING DATE: 2003-11-03
```

Art Unit: 1638

```
; NUMBER OF SEQ ID NOS: 64
; SOFTWARE: PatentIn version 3.2
; SEQ ID NO 2
; LENGTH: 415
; TYPE: DNA
; ORGANISM: Zea mays
; FEATURE:
; NAME/KEY: misc_feature
; OTHER INFORMATION: promoter Meg1-2
US-10-578-126-2
```

```
Query Match          74.4%; Score 275.4; DB 46; Length 415;
Best Local Similarity 89.7%; Pred. No. 3.1e-66;
Matches 349; Conservative 0; Mismatches 16; Indels 24; Gaps 4;
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```
Qy      1 AGCCAGAAATTGTAACCTTGGGGTTTCCCAACCTCAAATAGATATGGATATAGTTATATA 60
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      32 AGCCAGAAATTGTAACCTTGGGGTTTCCCAACCTCAAATAGATATAGATATAGGGATATA 91
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Qy      61 GATAGATATAGCAAAATTCACCAATAATATAGAGGTATAGATATAGATATAACAAGGGGT 120
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      92 GATAGATATAGCAAAATTCACCAATAATATAGAGGGTATAGATATAGATATAAGAAGGGGT 151
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Qy      121 ATATATATAGATATAGATATATAGAAGATATAGATGGATAGATAGATATGATAGAATAGA 180
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      152 ATAGATATAGATATAGATATATAGAAGATATAGATAGATAGATAGATATG-----ATAGA 206
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Qy      181 ATAGATAACTTACAATTTTGCTAAAAGAGAGACTAAATCACTGCTAAGTTTGG----- 232
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      207 ATAGATAACTTACAATTTTGCTAAAAGAACTAAATCACTGCTAAGTTTGGAGTAGCAT 266
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Qy      233 -TCTTTGGTGAATACTTGCCAGTGAATTGGTTTTCGCTATAG--TATATATATAAGTATA 289
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      267 ATCTTTGGTGAATACTTGCTAGTGAATTGGTTTTCGCTATAGTATATATATATAAGTATA 326
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Qy      290 CACTCTTCTAGGATTATAG-----TATATATAAGTATACACTCTTCTAGGATCGGTC 341
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      327 CACTCTTCTAGGATTATAGTATATATATATATAAGTATACACTCTTCTAGGATCAATC 386
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Qy      342 GTGAGGAGTTCCTTAACATTTCTTGGCGAC 370
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      387 GTGAGGAGTTCATTAAATTGCTTGGCGAC 415
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
```

RESULT 5

US-10-578-126-3

; Sequence 3, Application US/10578126

; GENERAL INFORMATION:

; APPLICANT: Perez, Pascual

; APPLICANT: Gutierrez-Marcos, Jose

; APPLICANT: Dickinson, Hugh

; TITLE OF INVENTION: MEGL Endosperm-Specific Promoter and Genes

; FILE REFERENCE: 11887*8

; CURRENT APPLICATION NUMBER: US/10/578,126

; CURRENT FILING DATE: 2006-05-02

; PRIOR APPLICATION NUMBER: PCT/EP04/052760

; PRIOR FILING DATE: 2004-11-04

; PRIOR APPLICATION NUMBER: EP 03292739.4

; PRIOR FILING DATE: 2003-11-03

Art Unit: 1638

```
; NUMBER OF SEQ ID NOS: 64
; SOFTWARE: PatentIn version 3.2
; SEQ ID NO 3
; LENGTH: 376
; TYPE: DNA
; ORGANISM: Zea mays
; FEATURE:
; NAME/KEY: misc_feature
; OTHER INFORMATION: promoter Megl-3
US-578-126-3
```

```

Query Match          65.8%; Score 243.6; DB 46; Length 376;
Best Local Similarity 87.0%; Pred. No. 2.5e-57;
Matches 322; Conservative 0; Mismatches 24; Indels 24; Gaps 4;

Qy      20  GGGTTTCCCACACCTCAAATAGATATGGATATAGTTTATATAGATAGATATAGCAAATTC 79
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      12  GGTATCGATAAGCCTCAAATAGATATAGATATAGGGATATAGATAGATATAGCAAATTC 71

Qy      80  CCAAATAATATAGAGGTATAGATATAGATATATAACAGGGGTATATATATAGATATAGATA 139
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      72  CCAAATAATATAGGGGTATAGATATAGATATATAAGAGGGGTATAGATATAGATATAGATA 131

Qy     140  TATAGAAGATATAGATGGATAGATAGATATGATAGAATAGAATAGATAACTTCACAATTTT 199
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db     132  TATAGAAGATATAGATAGATAGATAGATAGATG-----ATAGAATAGATAACTTACAATTTT 186

Qy     200  GTCTAAAAGAGACTAAATCACTGCTAAGTTTGG-----TCTTTGGTGAATACTTGC 250
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db     187  GTCTAAAAGAACTAAATCACTGCTAAGTTTGGAGTACGATATCTTTGGTGAATACTTGC 246

Qy     251  CAGTGAATTGGTTTTCGCTATAG--TATATATATAAGTATACACTCTTCTAGGATTATAG 308
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db     247  TAGTGAATTGGTTTCCGCTATAGTATATATATATAAGTATACACTCTTCTAGGATTATAG 306

Qy     309  -----TATATATAAGTATACACTCTTCTAGGATCGGTCGTGAGGAGTTCCTTAACAT 360
      ||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db     307  TATATATATATATAAGTATACACTCTTCTAGGATCAATCGTGAGGAGTTCATAAAATT 366

Qy     361  TTCTTGCGAC 370
      ||| | | | | |
Db     367  GTCTTGCGAC 376

```

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated endosperm specific promoter of SEQ ID NO: 1, does not reasonably provide enablement for sequences that hybridize to SEQ ID NO: 1, or sequence that have at least 70% sequence identity to SEQ ID NO: 1, or sequence that have some unspecified conserved sequence also found in SEQ ID NO: 1 all of which having endosperm specific

promoter activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to isolated polynucleotide sequences that have endosperm specific promoter activity and transformed plant cells and plants thereof and methods thereby.

Applicants teach SEQ ID NO: 1 having endosperm specific promoter activity.

Applicants do not teach hybridize to SEQ ID NO: 1, or sequence that have at least 70% sequence identity to SEQ ID NO: 1, or sequence that have some unspecified conserved sequence also found in SEQ ID NO: 1 all of which having endosperm specific promoter activity.

The state-of-the-art is such that one of skill in the art cannot predict the specific promoter activity based upon a limited set of descriptive portions i.e. conserved sequences because there are multiple interactions in the coordinate expression in endosperm tissue of maize (see Gutierrez-Marcos, J. *et al.* Phil. Trans. R. Soc. Lond. B (2003) 358, pp. 1105-1111). The authors state on page 7 in column 1 that additional cis elements are likely necessary for expression in the

basal part of the endosperm. Further, the elements required for specific expression may be held in common within a gene family, yet function in a different differently in a different context (i.e. within a different polynucleotide promoter sequence). Also see arguments *supra* under written description.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to make and use the invention. Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9-13 rejected under 35 U.S.C. 102(b) as being anticipated by Sevilla-Lecoq *et al.* Sex Plant Reprod (2003) vol. 16: 1-8.

The claims are broadly drawn to isolated polynucleotide sequences that have endosperm specific promoter activity having an unspecified conserved sequence and transformed plant cells and plant parts thereof.

Sevilla-Lecoq teaches particle bombardment of maize embryos with an expression construct comprising a ZmAE endosperm specific promoter (comprising a conserved feature) fused to the GUS coding region (see Results section beginning on page 3 to page 4 middle of column 2; also including Figure 1 on page 4).

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner, Art Unit 1638
August 17, 2009